

Claim 62
Sub E1 Cont

62. **(Twice amended)** A composition in the form of a gel comprising:
from greater than about 3% to about 8% of minoxidil;
from about 30% to about 80% of a polyol;
from about 10% to about 50% of an alcohol;
from about 0.01% to about 50% of a non-carbomeric polymer;
from about 0% to about 3% of a neutralizing agent; and
water (qs); wherein said minoxidil is substantially solubilized in said composition, and said
non-carbomeric polymer is other than hydroxypropyl cellulose.

Claim 79
Sub E1 Cont

79. **(Twice amended)** A non-gelled composition consisting essentially of minoxidil, a
thickening agent, and pharmaceutically acceptable solvent present in said composition in an
amount of at least about 20%, wherein said minoxidil is substantially solubilized in said
composition, and said composition is not in the form of an oil-in-water emulsion.

Claim 103
Sub E1 Cont

103. **(amended)** A composition of claim 79 which comprises from about 20% to about
99% solvent.

REMARKS

Applicants affirm the provisional election with traverse to prosecute the claims of
Group I, as made by David Cherry on November 1, 2002. Applicants respectfully request
that the claims of Group II, claims 105-109, be cancelled without prejudice, and expressly
reserve the right to pursue any canceled subject matter in a continuing or divisional
application. Upon entry of the above amendments, claims 1, 3-23, 25, 28-30, 33-36, 38-62,

64-76, 78-83, 85-87, 90-101, 103-104, and 111-118 will be pending. No new matter has been added.

Claims 1 and 62 have been amended to incorporate claims 2 and 63, respectively, and to define compositions “in the form of a gel.” Support for these amendments may also be found throughout the specification, for example, on page 4, line 24 through page 5, line 7. Claim 79 has been amended to incorporate claim 102 and to define compositions wherein the pharmaceutically acceptable solvent is present in “said composition in an amount of at least about 20%.” Support for this amendment may also be found throughout the specification, for example, on page 7, lines 7 through 16. Claim 103 has been amended to update the claim dependency in light of the cancellation of claim 102.

Applicants note and appreciate the Examiner’s withdrawal of the previous rejection of claim 36 under 35 U.S.C. § 112. The withdrawal of the rejection of claims 1-19, 21-23, 25-30, 33-36, 38-54, 56-72, 74-87, 90-100, and 102-117 under 35 U.S.C. 103(a) over Samour, Preuilh et al., and Pena and the rejection of claims 1-23, 25-30, 33-36, and 38-117 under 35 U.S.C. § 103(a) over Samour, Preuilh, and Pena in view of Grollier and Mousa is also acknowledged and appreciated.

Rejection under Section 112

Claim 119 stands rejected under 35 U.S.C. 112, second paragraph. Applicants have requested that this claim be cancelled. Therefore, this rejection is considered moot. Withdrawal of this rejection is respectfully requested.

Rejections under Section 102

Claims 1, 3-7, 11-14, 17-18, 21-23, 25-26, 28-30, 33-35, and 111 stand rejected as being anticipated under 35 U.S.C. § 102(e) by Preuilh et al. Applicants respectfully disagree with this rejection, for the reasons, for example, set forth in the response submitted on January 23, 2002. Nonetheless, in the interest of advancing prosecution of this application, Applicants have amended Claim 1 to recite that the claimed composition is in the form of a gel, to further distinguish the claimed invention from Preuilh. Preuilh is directed solely to oil-in-water emulsions. *See* Preuilh at column 1, lines 13-16. As set forth in the specification, for example at page 4, line 5 through page 5, line 6, emulsions are non-gelled compositions. As such, each and every claim limitation of the present invention is not taught by the reference as required by the law of anticipation. *Verdegaal Bros. v. Union Oil Co.*, 814 F. 2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 79-83, 85-86, 90-101, 104, and 117 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.K Patent Application 2,194,887 to Grollier et al. Applicants also respectfully disagree with this rejection. Grollier requires that the minoxidil be present in an a concentration of at least its solubility limit, and preferably above its solubility limit, so that particles of unsolubilized minoxidil are present in the composition. *See* Grollier at page 2, lines 25 through 27. Applicants' claims, on the other hand, define compositions in which the minoxidil is "substantially solubilized." This term is explicitly defined in the specification as meaning that the minoxidil is present "at a concentration which is less than about its solubility limit." See page 6, lines 15 through 17.

Moreover, claim 79, as amended herein, defines compositions that contain at least about 20% solvent, which further distinguishes the claimed invention from Grollier. Grollier

teaches compositions that contain less than 20% solvent. *See* Grollier at page 2, lines 35-38. Accordingly, Applicants respectfully submit that Grollier does not anticipate any of claims 79-83, 85-86, 90-101, 104, and 117, and respectfully request reconsideration and withdrawal of this rejection.

Claim 119 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Samour. Without conceding to this rejection, Applicants have requested cancellation of this claim, without prejudice. This rejection is respectfully considered moot.

Rejections under Section 103

Claims 2, 8-10, 15-16, 36, 38-52, 56-70, 74-76, 78, and 112-116 as being unpatentable over Preuilh and further in view of Samour and U.S. Patent No. 6,423,329 to Sine et al. Applicants respectfully traverse this rejection. Preuilh does not teach Applicants' compositions in a manner sufficient to place one skilled in the art in possession of the claimed subject manner as required by the law of anticipation (as noted above) and obviousness. Although the Office Action is of the opinion that Samour discloses gels that may have "0.05-5% minoxidil," see Office Action at page 7, Preuilh teaches only oil-in-water emulsions, which are non-gelled compositions. Accordingly, Preuilh teaches away from Applicants' claimed invention. Although Samour may teach the preparation of gels, the Office Action has shown no motivation as to why one skilled in the art would ignore the teachings of either reference and combine the two. Moreover, it is not clear how one would combine the teachings to in any way arrive at the compositions defined by Applicants' claims, and thus no reasonable expectation of success is provided. Applicants respectfully submit that without such a showing of motivation to combine and a reasonable expectation of success, this rejection should be withdrawn.

Even if one were granted motivation to combine the two references, Samour would

not provide the claimed invention when combined with Preuilh as there is no showing of a gelled composition having greater than 3% minoxidil in Samour. The only gelled compositions exemplified in Samour are either 1.0% or 2.0% minoxidil. *See* Samour at column 6, line 55 to column 7, line 25. As discussed in the Response filed July 31, 2002, given the difficulty in producing compositions above 3% minoxidil, a more specific showing of the compositions having greater than 3% minoxidil is necessary. As is, the disclosure relied upon by the Office Action does not teach or suggest the claimed invention.

In addition to Preuilh and Samour, the Office Action applies Sine although there is no teaching of minoxidil use or using any composition on the scalp to treat hair follicles. There is no motivation as to why one skilled in the art would look to the Sine reference to solve problems relating to treatment of the scalp and hair as in Preuilh (column. 1, lines 21 to 29) or Samour (Abstract).

The addition of Sine with Preuilh and Samour does not address the failure of compositions containing higher concentrations of minoxidil to make pharmaceutically elegant compositions for hair use as addressed in the present application. Sine only teaches compositions and methods of sanitation and moisturizing for use on the skin. The present invention is for use on hair. Carbopol® 940 along with the other resins noted above are carboomers as defined by applicants in the present specification on page 9, lines 6 to 13. Claims 1 and 62 (as amended herein) of the present invention and the claims dependent therefrom are distinguishable over Preuilh in view of Samour and Sine at least because they define compositions in the form of a gel having a **non-carbomeric thickening agent or polymer**. Sine also has no mention of minoxidil or any other pharmaceutically active agent used in its compositions.

Moreover, since Preuilh *teaches away* from Applicants' claimed gelled compositions,

any rejection based upon the combination of Preuilh with the other two references is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection in light of the above comments.

Applicants also request withdrawal of the rejection of claims 19-20 and 53-55 as being unpatentable over Preuilh and further in view of U.S. Patent No. 5,798,426 to Anton et al. and Grollier. As discussed above, Preuilh *teaches away* from the claimed invention. Grollier also teaches away from the claimed invention, since, as discussed above, Grollier teaches that the minoxidil is present in a concentration of at least the solubility limit for minoxidil, while the instant claims define compositions in which the minoxidil is substantially solubilized. The combination of Anton with these two references that *teach away* from the claimed invention, is therefore improper. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The rejection of claims 71-73 as being unpatentable over Preuilh in view of Samour and Sine and further in view of Anton and Grollier should also be withdrawn. Applicants have amended claim 62, from which claims 71-73 depend, to define a composition in the form of a gel. In light of the above arguments and claim amendments, Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants request reconsideration of the rejection of claim 87 as being unpatentable over Grollier and further in view of Sine and Preuilh. The claims are not unpatentable as Grollier does not teach or suggest all of the claim limitations of the present invention as required by the law of obviousness. *See* MPEP § 2143.03. As noted above, Grollier requires that the minoxidil be present in the composition in a concentration of at least its solubility limit. Moreover, Applicants have requested amendment of claim 79, from which claim 87 depends, to define compositions having at least about 20% solvent. Grollier does not place

one skilled in the art in possession of the invention because it teaches compositions having less than 20% solvent. The addition of Sine does not remedy this shortcoming as there is no motivation to combine Sine with the teaching of Grollier. Sine teaches the compositions for use in sanitation and moisturizing the skin and makes no mention of using minoxidil for the treatment of hair follicles. One skilled in the art using only the art accepted wisdom of the time and without the benefit of the present application would not combine Sine with Grollier to obtain any claimed invention. Without such a showing, Applicants respectfully submit that the combination of these references is improper.

Moreover, even if these references are combined, the use of thickening agents described by Sine fails to overcome Grollier's express teaching to include minoxidil at concentrations that assure that the minoxidil is not substantially solubilized, as required by Applicants' claims. Applicants respectfully request, therefore, that the rejection under Section 103 over Grollier in view of Sine be reconsidered and withdrawn.

The rejection of claims 102-103 as being unpatentable over Grollier and further in view of Samour should also be reconsidered. Claim 103 remains rejected as Applicants have requested cancellation of claim 102. The rejection should be reconsidered as the Office Action does not provide a sufficient motivation for combining Grollier and Samour. As noted above, Grollier *teaches away* from the claimed invention by teaching only compositions in which the minoxidil is not substantially solubilized, as required by Applicants' claims. Moreover, Grollier pertains to compositions having less than 20% solvent, whereas the compositions of the present invention have at least 20% solvent. Although the Office Action puts forth Samour as a remedy to this shortcoming, it does so by taking the position that both references are directed to "compositions comprising 0.2-5% minoxidil." *See* Office Action at page 12. However, the Applicants have noted the difficulty

in making pharmaceutically elegant compositions at higher concentrations of minoxidil. Therefore, one skilled in the art would not be motivated to combine the two references as neither offers a solution to making pharmaceutically elegant compositions having higher concentrations of minoxidil. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection in light of the cancellation of claim 102 and the above arguments.

Miscellaneous

The Office Action states that the recitations “high solvent/low water gelled” and “high solvent/low water, pharmaceutically elegant gelled” in claims 36 and 119 have not been given patentable weight because they merely recite the intended use of the structure. However, these recitations do not recite the intended use of the structure. These compositions have more than about 50% solvent and/or less than about 25% water as defined in the claims and in the specification on page 9, lines 26 to 28. In claims directed to articles and apparatuses, any phraseology in the preamble that limits the structure of that article or apparatus must be given weight. *In re Stencel*, 828 F.2d 150, 4 U.S.P.Q. 2d 1071 (Fed. Cir. 1987); M.P.E.P. 2111.02. It is only by these phrases does one know that the compositions defined by the claims are high solvent/low water, pharmaceutically elegant gels. *See Kropa v. Robie*, 187 F.2d 150, 152, 88 U.S.P.Q. 478, 481 (C.C.P.A. 1951)(Court ruled that the phrase “an abrasive article” was essential to the claim because only by that phrase could the subject matter of the claim be known.”); MPEP § 2111.02. Applicants submit that the above recitations should be given patentable weight with respect to claim 36 as Applicants have requested cancellation of claim 119.

Upon review of the separate rejections within the Detailed Action, it is noted that

claim 118 has not been rejected, although listed as such on the Office Action Summary.

Applicants respectfully request clarification of the status of this claim.

Applicants also request consideration of claims 27, 77, 84, 88, 89, and 105-109 that were previously withdrawn from consideration.

Conclusion

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

Date:

February 20, 2003



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VERSION WITH MARKINGS TO SHOW CHANGES MADE**In the claims:**

Please cancel claims 2, 63, 102, 105-109, and 119 without prejudice and amend claims 1, 62, 79, and 103 as shown:

1. **(Twice amended)** A composition in the form of a gel comprising minoxidil, a non-carbomeric organic thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is substantially solubilized in said composition, and said non-carbomeric thickening agents is other than hydroxypropyl cellulose.

62. **(Twice amended)** A composition in the form of a gel comprising:
 - from greater than about 3% to about 8% of minoxidil;
 - from about 30% to about 80% of a polyol;
 - from about 10% to about 50% of an alcohol;
 - from about 0.01% to about 50% of a non-carbomeric polymer;
 - from about 0% to about 3% of a neutralizing agent; andwater (qs); wherein said minoxidil is substantially solubilized in said composition, and said non-carbomeric polymer is other than hydroxypropyl cellulose.

79. **(Twice amended)** A non-gelled composition consisting essentially of minoxidil, a thickening agent, and pharmaceutically acceptable solvent present in said composition in an amount of at least about 20%, wherein said minoxidil is substantially solubilized in said composition, and said composition is not in the form of an oil-in-water emulsion.

103. (amended) A composition of claim [102] 79 which comprises from about 20% to about 99% solvent.